

**LIBELED:** 3-18-54, S. Dist. N. Y.

**CHARGE:** 501 (c)—the quality of the article when shipped fell below that which it purported and was represented to possess; and, 502 (a)—the label statements "Prophylactic" and "For the prevention of disease" were false and misleading as applied to an article containing holes.

**DISPOSITION:** Irving L. Schechter, New Haven, Conn., appeared as claimant, after which the case came on for hearing before the court on the Government's motion for a final decree. After hearing the arguments of the Government counsel in support of the motion and of the claimant in opposition thereto, the court, on 1-28-55, entered a decree of condemnation and destruction.

### DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS\*

**4654. Drugs (a brownish black liquid and a pink liquid) for use in the treatment of cancer. (Inj. No. 232.)**

**COMPLAINT FOR INJUNCTION FILED:** November 16, 1950, Northern District of Texas, against Hoxsey Cancer Clinic, a partnership, Dallas, Tex., and Harry M. Hoxsey, to enjoin the interstate shipment of the above-mentioned drugs misbranded as hereinafter described.

**CHARGE:** The material allegations of the complaint are stated in the decision of the court of December 21, 1950, set forth below.

**DISPOSITION:** The defendants filed an answer denying the material allegations of the complaint; and, on December 14, 1950, the case came on for trial before the court without a jury. The trial was concluded on December 20, 1950; and, on the following day, the court handed down its decision, together with the following findings of fact and conclusions of law:

*ATWELL, District Judge:* "On November 15th, 1950, this complaint was filed, charging that the proceeding is brought under Sec. 302 (a) of the Food and Drug Act, 21 U. S. C. 332 (a).

"That the respondents have been and are now introducing and causing to be introduced, and delivering and causing to be delivered for introduction into interstate commerce, at Dallas, Tex., in violation of Sec. 301 (a) of the Act, and 21 U. S. C. 331 (a) consignments of articles of drug within the meaning of Sec. 201 (g) of said Act, which are misbranded within the meaning of Sec. 302 of the Act.

"That the respondents promote the sale of, distribute and deliver such articles of drug from their clinic at Dallas, Texas, to physicians, and, practitioners in other portions in various parts of the United States. That such articles consist of liquids, intended for use in the mitigation, treatment and cure of cancer in man. One of such liquids is brownish-black in color, and the other, pink. Such liquids are dispatched in interstate commerce in sixteen-ounce bottles and bear the label on which appears essentially the following, to-wit:

H. C. C. 4507 Gaston Ave., Dallas Texas, -----  
No. ----- Dr. ----- One teaspoonful after  
meals and at bedtime. Keep cool.

That in some instances, a number appears following, 'No.' In some instances the name of J. B. Durkee appears following, 'Dr.' That the respondents in the distribution and delivery of such drugs to physicians and practitioners, dispatch such brownish-black and pink liquids in concentrated form also in sixteen-ounce bottles. The brownish-black concentrate bears a label on which appears,

From: Hoxsey Cancer Clinic 4507 Gaston Av.,  
Dallas, Texas. To: Regular concentrate add  
enough water to make one gallon. Shake well.

\*See also Nos. 4641, 4647-4649, 4651-4653.

The pink concentrate bears a label on which appears,

From: Hoxsey Cancer Clinic 4507 Gaston Ave.,  
Dallas, Texas. To: Lactate Concentrate Add  
enough Lactate to make one gallon Shake well.

"That consignments of said drugs which are distributed and dispatched to physicians, practitioners, and other persons by the respondents are misbranded within the meaning of Sec. 502 (a) of the Act (21 U. S. C. 352 (a)) in that their labeling, namely, the booklet entitled, 'Hoxsey Cancer Clinic Specializing in Cancer,' accompanying said drugs, contains general and specific statements which represent and suggest that said drugs are efficacious in the treatment, mitigation and cure of cancer in man, which statements are false and misleading since said drugs are not efficacious in the treatment, mitigation and cure of cancer in man.

"That complainant is informed and believes that unless restrained by the court the respondents will continue to introduce and cause to be introduced and deliver and cause to be delivered for introduction into interstate commerce the said drugs misbranded in the manner aforesaid.

"Complainant then prays for a perpetual injunction from directly or indirectly introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, the said drugs or any similar article of drug which is misbranded within the meaning of the Act.

"On December 5th, 1950, the respondents denied the allegations and, in that connection, said that respondents do specialize in the treatment of cancer which is done under the direction of duly licensed doctors; that they do not sell medicine, offer none for sale, and do not sell nor distribute medicine to the public.

"That the allegations that they promote the sale, or, distribution, or, deliver drugs to physicians and practitioners in other parts of the United States, they deny.

"They plead that any medicine shipped by them is that medicine which has been prescribed by a doctor and sent to a patient who is under treatment; that no patient received medicine from the clinic until after said patient had appeared in person and after having been examined by the Medical Director of the clinic, which medical examination includes blood tests, urinalysis and x-ray studies, and after said examination a prescription is made by said doctor. That the respondents have no medicine for sale and do not offer medicine for sale, nor does it advertise or distribute medicine.

"Respondents deny that the booklet referred to by complainant is a label within the meaning of the Food and Drug Act. That the booklet nowhere mentions any particular medicine, nor is the same an advertisement of the medicine. Nor is it the booklet now sent out by the respondents, but is one formerly mailed by respondents and that the booklet which is complained of by the complainant specifically refutes what complainant has alleged.

"That in this connection, the first six pages of said booklet contain an address by Dr. Durkee made in Los Angeles, California, on October 17th, 1947, which, among other things, says:

The Hoxsey method of treatment is designed primarily to normalize the body chemistry and control normal cell metabolism—it would be well at this point to tell you about our physical equipment and our method of approach in treating a person who has cancer. Our clinic is equipped with the best diagnostic facilities obtainable. When a patient enters our clinic every laboratory procedure is used—our treatment consists basically of two groups of medications plus the supportive treatment that may be necessary.

Our treatment is designed to normalize first of all the inorganic blood chemistry—we are able to show in our laboratory the changes in the blood chemistry of the patient as he undergoes treatment.

"The booklet, on page 7, among other things, contains the following:

The Hoxsey method of treatment is not a cure-all, nor does the clinic guarantee to cure any case, which is the practice of quacks and charlatans—Patients must come to the clinic for a complete examination and laboratory analysis.

"That the foregoing quotations are not isolated statements, but are representative of the matters and things contained throughout said booklet, to-wit: a partial description of the Hoxsey method of treatment of cancer.

"I have quoted and summarized rather fully the pleadings of each side in order to give to each side that fairness of word picture which the importance of the case justifies and demands.

"After six days of the introduction of voluminous verbal testimony from both physician and patient, for both sides, and voluminous exhibit from both sides, and, having in mind the court's duty to pass upon the burden of proof, the weight of the testimony, and the credibility of the witness, I make the following

#### FINDINGS OF FACT

1.

"The respondent did forward in interstate commerce to physicians in other States who had been present at the Hoxsey Clinic and studied its methods and efficacy for a considerable time, and were using such medicines and prescriptions in their similar treatment.

2.

"That accompanying such shipments were booklets containing the statements and illustrations quoted in the pleadings of both complaint and respondents.

3.

"That the respondents' treatment is not injurious. Some it cures, and some it does not cure, and, some it relieves somewhat. That respondents do not guarantee to cure.

4.

"That the statements contained in said labels so pleaded, are neither false nor misleading. That if in doubt as to the effectuality of the treatment, they take the patient on trial, and, frequently, without charge to the patient.

5.

"That the percentage of efficient and beneficial treatments by respondents is reasonably comparable to the efficiency and success of surgery and radium, and without the physical suffering and dire consequences of radium, if improperly administered, and surgery, if not successful in completely removing the entire malignant portion.

6.

"That cancer is an aggregation of outlaw cells with the propensity to migrate and grow in size and in the territory covered and the definite destruction of the body, or, a serious portion thereof.

7.

"That the respondents do have two basic medicines to which are added, if and when the examination of the patient calls for such additions, a large number of drugs and medications in a separate room at the clinic. That it also subtracts and changes the basic elements of the two medicines as indicated, in the judgment of the Medical Director of the clinic when indicated by the examination of the patient, but that no such prescription accompanies shipments made in interstate commerce to the doctors in other States who are using the Hoxsey method, nor does the same appear upon the bottles or receptacles of the medicine.

8.

"That the Food and Drug inspectors seized medicines and pamphlets and booklets such as are pleaded, from the doctors in other States who have been

using the Hoxsey method, and which came interstate commerce. That such seizures were prior to the institution of this suit, since which time the respondents have made no interstate shipments of either pamphlets, or, medicines.

#### CONCLUSIONS OF LAW

"It is not necessary that mislabeling, or, misbranding within the meaning of the Act, shall actually be on the container, but they may accompany it, or, reach the user in some other manner. There is some authority to the contrary, but I think the case of *Kordel v. United States*, 335 U. S. 345, and the case of *United States v. Urbuteit*, 335 U. S. 355, are controlling.

"The exemptions provided for in the Act with reference to physicians' prescriptions, and the placing of the contents on the bottle, or, container, are not applicable, nor can they be of any use to the respondents here, because the respondents' method in forwarding articles and pamphlets to the physicians in other States who are using the method and treatments were not so displayed. Nor can the plea of good faith, or, the charitable inclinations of the respondents save them from the rigors of the Act. Nor can the discontinuance of the practice of shipments to physicians in other States, save the respondents from the injunctive features of the Act, even though the chancellor, speaking in equity, will not require that which is useless.

"Nevertheless, the facts disclosed by the testimony and found as above, as well as the failure of the government to successfully carry the burden and show by a preponderance of the testimony, the correctness of its charges, merits, and must have, a refusal of the injunctive relief sought, and a dismissal of the bill, and such order and decree is, accordingly, announced."

On February 15, 1951, a notice of appeal to the United States Court of Appeals for the Fifth Circuit was filed by the Government; and, on July 31, 1952, after considering the briefs and arguments of counsel, the following opinion was handed down by that court (198 F 2d 273) :

RUSSELL, *Circuit Judge*: "Proceeding under the provisions of the Federal Food, Drug and Cosmetic Act,<sup>1</sup> and relying particularly upon its provisions defining labeling,<sup>2</sup> prohibiting introduction into interstate commerce of any drug that is misbranded,<sup>3</sup> and deeming a drug misbranded 'If its labeling is false or misleading in any particular,'<sup>4</sup> the United States sought in the trial Court the injunctive relief provided by the Act<sup>5</sup> to prevent the Hoxsey Cancer Clinic, and Harry M. Hoxsey, from introducing or delivering for introduction into interstate commerce bottles of brownish-black, and pink, colored liquids intended for use in the treatment and cure of cancer in man. It is alleged that the drugs, which are distributed and dispatched to physicians, practitioners, and other persons, by defendants are misbranded, because their labeling, specifically a booklet accompanying them, contains 'general and specific statements which represent and suggest that said drugs are efficacious in the treatment, mitigation and cure of cancer in man, which statements are false and misleading since said drugs are not efficacious in the treatment, mitigation and cure of cancer in man.' Two substantially similar booklets are involved, though it appears that one is no longer used.

"For the establishment of its claims of general false and misleading statements, the Government relies upon the import and effect of statements made in an address, captioned: 'Theory and Application of the Hoxsey Method of Treating Cancer,' by 'J. B. Durkee, D. O., Medical Director of the Hoxsey Cancer Clinic, Dallas, Texas, before the Second Annual Convention of the National Medical Society October 17, 1947, held at Royal Palms Hotel, Los Angeles, Calif.,' reprinted in the booklets, as well as other statements and representations of the booklets which represent that the Hoxsey medicines are effective in the cure, mitigation, or treatment of internal cancer.

<sup>1</sup> 21 U. S. C. 301, et seq.

<sup>2</sup> 21 U. S. C. 321 (m).

<sup>3</sup> 21 U. S. C. 331 (a).

<sup>4</sup> 21 U. S. C. 352 (a).

<sup>5</sup> 21 U. S. C. 332.

"The claim of specific misrepresentations is predicated upon the contention that a division of the contents of the booklet, which includes the listing of individuals with their post office address and statement of the portion of the body on which the cancer appeared, reprint of proceedings and testimony of patients thereupon given, 'before and after' treatment photographs and comment thereon, and the invitation to write to the individuals listed 'requesting first hand testimony regarding our treatment' when read in conjunction with the statement 'we wish only to present the facts and records of results and benefits received by those who have taken our treatment' \* \* \* leaves the clear representation that the persons named were cured of cancer by the Hoxsey drugs.' The truth is said to be that 'any of these specific representations are downright falsehoods.'

"The defense, in the trial Court by pleading and testimony, and renewed hereby argument and brief, challenges each and all of the Government's contentions. The position of the defendants is that, as to the claim of general representations, the contents and statements of the booklets, considered as a whole, expressly deny that the medicines will cure all cases, but only that they cure some, do not cure some, and 'relieve some somewhat.' As to the specific charges of misbranding, the defendants' argument is mainly that by use of the word 'patients' in reference to the individuals listed in the booklet there is removed any idea that such persons have been cured. However, it is further contended that the testimony does show that many of the listed individuals were successfully treated and, in some instances, cured. Underlying the entire argument is the fundamental contention that the medicines in question are efficacious in some instances in the cure and alleviation of cancer, and that they represent a 'revolutionary treatment,' which is, in many cases, successful. Running through the entire defense is the claim that the medicines and supportive treatments produce a higher percentage of more satisfactory results in the treatment of cancer than is secured by the other methods of treatment more generally employed of either X-ray, surgery, radium, or, in some instances, use of some of the by-products of atomic bomb production. These so-called orthodox methods are criticised as ineffective and in some cases positively harmful, whereas defendants contend their treatment does not have such harmful results and yet secures a higher percentage of cures.

"The issues thus arising are still present here and require for their solution determination of what representations, general or specific, the booklets may fairly and reasonably be determined to make in the circumstances to which they relate and to the persons to whom they were made, and whether, as so construed and found, the representations are false and misleading within the terms of the statute. Implicit in the latter, and actually controlling here, is whether the Government maintained either or both of its positions that the medicines in question were not efficacious in the cure of cancer in man, and that, in any event, assuming that its claim of specific representation had been established, it had proved such representation to be false.

"The trial Court made findings of fact and entered conclusions of law,<sup>6</sup> and, upon the ultimate ground that under the testimony as a whole the Govern-

<sup>6</sup> "FINDINGS OF FACT—

1.

"The respondent did forward in interstate commerce to physicians in other states who had been present at the Hoxsey Clinic and studied its methods and efficacy for a considerable time, and were using such medicines and prescriptions in their similar treatment.

2.

"That accompanying such shipments were booklets containing the statements and illustrations quoted in the pleadings of both complainant and respondents.

3.

"That the respondents' treatment is not injurious. Some it cures, and some it does not cure, and, some it relieves somewhat. That respondents do not guarantee to cure.

4.

"That the statements contained in said labels so pleaded, are neither false nor

ment had failed to show the correctness of its charges, concluded that the injunctive relief sought should be denied.

"The Government, as appellant here, strenuously insists that the trial Court's findings and conclusions evidence misapprehension of the legal effect of the competent evidence, as well as failure to apply the controlling law. It is urged that the competent evidence in the case presents undisputed proof of the Government's specific charges of misbranding which entitled the Government to a decree in its favor; that the Court's findings were erroneously induced by consideration of, and reliance upon, incompetent testimony from laymen that they had cancer; and that they were cured; and that the controlling finding by the trial Court that the Hoxsey drugs are not falsely represented as cancer cures and that they do cure cancer are clearly erroneous, should be set aside, and the issuance of an injunction directed by this Court. Appellees relying upon the Court's finding that the treatment 'cures some, and some it does not cure, and some it relieves somewhat. That respondents do not guarantee to cure,' cite it as confirmation of the finding that the representations of the booklet are neither false nor misleading.

"Our consideration of the booklets, which concededly constitute the labeling referred to by the statute,<sup>7</sup> leaves us in no doubt that as concerns the nature and extent of general representation the content and statements of the booklet are intended to, and do, convey the claim that the Hoxsey medicines present a

misleading. That if in doubt as to the effectuality of the treatment, they take the patient on trial, and frequently, without charge to the patient.

5.

"That the percentage of efficient and beneficial treatments by respondents is reasonably comparable to the efficiency and success of surgery and radium, and without the physical suffering and dire consequences of radium, if improperly administered, and surgery, if not successful in completely removing the entire malignant portion.

6.

"That cancer is an aggregation of outlaw cells with the propensity to migrate and grow in size and in the territory covered and the definite destruction of the body, or, a serious portion thereof.

7.

"That the respondents do have two basic medicines to which are added, if and when the examination of the patient calls for such additions, a large number of drugs and medications in a separate room at the clinic. That it also subtracts and changes the basic elements of the two medicines as indicated, in the judgment of the Medical Director of the clinic when indicated by the examination of the patient, but that no such prescription accompanies shipments made in interstate commerce to the doctors in other states who are using the Hoxsey method, nor does the same appear upon the bottles or receptacles of the medicine.

8.

"That the Food and Drug Inspectors seized medicines and pamphlets and booklets such as are pleaded, from the doctors in other states who have been using the Hoxsey method, and which came interstate commerce. That such seizures were prior to the institution of this suit, since which time the respondents have made no interstate shipments of either pamphlets, or, medicines.

"CONCLUSIONS OF LAW—

"It is not necessary that mislabeling, or, misbrandings within the meaning of the Act shall actually be on the container, but they may accompany it, or, reach the user in some other manner. There is some authority to the contrary, but I think the case of *Kordel v. United States*, 335 U. S. 345, and the case of *United States v. Urbuteit*, 335 U. S. 355, are controlling.

"The exemptions provided for in the Act with reference to physicians' prescriptions, and the placing of the contents on the bottle, or, container, are not applicable, nor can they be of any use to the respondents here, because the respondents' method in forwarding articles and pamphlets to the physicians in other states who were using the method and treatments were not so displayed. Nor can the plea of good faith, or, the charitable inclinations of the respondents save them from the rigors of the Act. Nor can the discontinuance of the practice of shipments to physicians in other states, save the respondents from the injunctive features of the Act, even though the Chancellor, speaking in equity, will not require that which is useless.

"Nevertheless, the facts disclosed by the testimony and found as above, as well as the failure of the government to successfully carry the burden and show a preponderance of the testimony, the correctness of its charges, merits, and must have, a refusal of the injunctive relief sought, and a dismissal of the bill, and such order and decree is, accordingly, announced."

<sup>7</sup> *Kordel v. United States*, 335 U. S. 345; *United States v. Urbuteit*, 335 U. S. 355.

successful cure for cancer in only some cases, but the recitation of their virtues is so emphasized and reiterated as to induce in the mind of one thinking he suffered from cancer a belief that he had an excellent chance to be one of those cases in which the medicine would be successful. The language and entire contents are so hedged about with denials that the treatment is a 'cure-all,' or effective in all cases, that its true import is only that the medicines are effective in a substantial number of cases. For the purpose of this decision, and in determining the truth of such representations, we will accept the more restricted position, to which the Government is driven, that the precise extent of successful cures is immaterial since, it is contended, that the representation that *any cure* can be effected by use of the medicines is false and misleading. We think the claim of specific representation that the parties listed and given as references for testimonials is sustained to the extent claimed by the Government. It is difficult to imagine that one thinking himself afflicted with the dire disease of cancer and reading and considering the references to these listed patients, and the testimony there set forth, and which is prefaced as this is<sup>8</sup> and reiterated by conclusion,<sup>9</sup> would reach any other conclusion than that the persons listed were cured of cancer by the Hoxsey drugs. It is common knowledge that such is the representation of 'testimonial letters as is the usual custom.' It is clear that the general representation is that at least the Hoxsey medicines will cure some cancer, and the specific representation is that it has cured the persons listed as patients, and who have testified as to cure, and to whom it is suggested letters be addressed to obtain testimonials to the efficacy of such medicines. The question of whether these representations are false and misleading remains.

"In approaching this question we are guided by some well recognized beliefs and experience so universally entertained and accepted by the practically unanimous aggregate of medical science as that contradiction thereof does not raise a substantial issue of fact. Thus, with practical unanimity, those informed and in position to know are of the firm belief that there is only one reliable and accurate means of determining whether what is thought to be cancer is, in truth and fact, actually cancer. This requires a biopsy, a microscopic examination of a piece of tissue removed from the infected and question diseased region. From this it follows that the opinion of a layman as to whether he has, or had, cancer, or a like opinion as to whether he has been cured and no longer bears the disease, if, in fact, it ever actually existed, is entitled to little, if any, weight. It is further true that despite the vast and continuous research which has been conducted into the cause of, and possible cure for, cancer the aggregate of medical experience and qualified experts recognize in the treatment of internal cancer only the methods of surgery, X-ray, radium and some of the radio-active by-products of atomic bomb production. This is so even though the ghastly truth is that these methods frequently fail and are, in many cases, themselves unsatisfactory. But it is true, nevertheless, that with present enlightenment they are our sole defense against the scourge of cancer. We think this statement evidences no acceptance of any particular school or segment of qualified expert medical opinion and belief, though it is not to say that persons activated by self-interest or ignorance may be found to express a contrary opinion. It is to say, however, that upon such subjects a Court should not be so blind and deaf as to fail to see, hear and understand the import and effect of such matters of general public knowledge and acceptance, especially where they are established by the overwhelming weight of disinterested testimony as appears in the record now before us.

"Two liquid medicines which are shown to have been distributed by the defendants in interstate commerce for use in treatment of cancer are involved

<sup>8</sup> "We are not going to use printed space for testimonial letters as is the usual custom, however, you will find a list of patients following, with cases no doubt paralleling your own. We are giving you their names and addresses. If you will write, enclosing a self-addressed, stamped envelope we feel you will receive a testimonial first-hand."

<sup>9</sup> "Space does not permit us to give a complete list of all our patients, therefore, we have selected the above cases for the reason that they represent a cross section of the various types of patients treated at this institution.

"You will no doubt find in this list a condition similar to that with which you or some member of the family are afflicted. We would suggest that you correspond with some of these patients, enclosing a self-addressed envelope, requesting first-hand testimony regarding our treatment."

in this action.<sup>10</sup> One is a black, or brownish-black mixture; the other a pink medicine. Their respective formulae are neither secret nor contested. The analysis of samples of the drugs showed that the proportion of ingredients of the black medicine varied, but contained potassium iodide and extracts, (omitting the scientific names), from prickly ash bark, buckthorn, red clover blossom, alfalfa, and cascara sagrada. The pink medicine contained potassium iodide and lactate of pepsin. These drugs are shipped in 16-ounce bottles, to patients in diluted form, and to osteopaths in concentrated form with direction to add enough water (in case of the black), or elixir of pepsin (in case of the pink), to make a gallon. Illustrative analyses of the dilution are: water, 62 percent, potassium iodide, 26.4 percent, plant extractives, 7.9 percent, mineral matter other than potassium iodide, 6/10ths of 1 percent, and licorice flavoring; another, water, 53.2 percent, alcohol, 5.1 percent, sugars, 12/6 percent, potassium iodide, 29½ percent, and the presence of pepsin; another, water, 94½ percent, potassium iodide, 4½ percent, plant extractives, 9/10ths of 1 percent, and the presence of a licorice like flavoring; another, water, 76 percent, alcohol, 7.2 percent, sugars, 15 percent, potassium iodide, 1.3 percent and the presence of pepsin, and this was a 'slightly acid preparation.' The source of supply is the Hoxsey Cancer Clinic in Dallas, Texas. The defendant, Harry M. Hoxsey, is not a doctor, but a layman. It is his claim that the Hoxsey cancer drugs were originated by his grandfather about 1840 in Kentucky; were later used by his son, the defendant's father, and after the defendant's father's death in 1919 the present Mr. Hoxsey carried on the treatment and preparation of the drugs at the clinic, which was in charge of a doctor. The present director is Dr. J. B. Durkee, a doctor of osteopathy. The clinic operates through osteopaths and the drugs may be obtained from the clinic in Dallas, or from osteopaths in other states who have obtained the medicines by shipments from the clinic. The clinic does not maintain hospital facilities and patients who go there for treatment take the medicines away with them for self-administration. Supplies are replenished by shipments of the medicines to them.

"Upon the trial the Government, after establishing the interstate shipments of drugs and booklets, and testimony as to the formulae and analyses of the drugs in question, introduced the testimony of highly qualified and experienced experts as to the pharmacological and pathological reaction and effect of the drugs in the Hoxsey medicines. Dr. David I. Macht, a physician specializing in pharmacological and experimental therapeutics, with impressive qualifications, who has done work on potassium iodide and emodin bearing drugs such as cascara sagrada and buckthorn, testified that potassium iodide could cause untoward reactions in most people. The amount received from the black medicine, when taken as recommended, could cause damage in some people. There is no basis for therapeutic use of the drugs found in the medicines, or any combination of them in the treatment of cancer. A pathologist, Dr. Max A. Goldzieher, likewise qualified and experienced in his specialty, had conducted extensive research in cancer and in connection with his research had studied and experimented in the use of potassium in cancer in afflicted animals and also upon a group of 27 volunteer patients, all of whom were 'very far gone, inoperable and obviously incurable cases of cancer.' From these studies and experiments, he concluded that potassium increases the rate of growth in cancer and is not advisable in cancerous patients. It was his opinion, based upon such experiments, that the result of a patient with a malignant growth taking a daily dose as prescribed of the Hoxsey medicine would be to speed the growth of the cancer. Testimony was also presented of a controlled laboratory experiment carried out at the Jackson Memorial Laboratories, Bar Harbor, Maine, an institution engaged in the fundamental research of the biology of cancer, to show the effects of both types of Hoxsey medicine in treating cancerous mice. The physicians and scientists participating in the test possessed superior qualifications and extensive experience in such matters. It is shown that the manner and method of such experiments was in accord-

<sup>10</sup> Throughout the booklets referred to, and in the testimony, there are references to external, or skin cancers also. The defendants, in addition to the liquid medicines for the treatment of internal cancer, also have an escharotic treatment for external, or skin, cancer. This consists of a corrosive or caustic substance the basic ingredient of which is arsenic. The Government makes no contention as to this medicine, or with reference to external cancer, and consequently this medicine and the question of its use and efficacy in the treatment and cure of external cancers, and, in fact, the entire subject of external cancers is not here involved.



ance with the best known and accepted practice and was applicable to the treatment of cancer in humans to the extent that 'those agents which have been shown to produce beneficial effects against cancer in man, in general have been—they produce definite beneficial effects in some cancer on experimental animals.' The Hoxsey medication had no beneficial therapeutic effect on the cancer of the afflicted mice. It was testified by Dr. R. L. Clark, an expert of superior qualification and experience, that the recognized and only accurate method of diagnosing cancer is by a biopsy examination of the tissue, made by someone who has made a special study of the process. He stated that he knew of no medicine taken orally that would cure cancer, and he considers that there are two different methods of curing cancer known today, 'one of them is by removing the tumor by surgery, generally, and the other one is by using radiation therapy, which constitutes X-ray, radium, and more recently some of the products, by-products, of the atomic bomb production.' This witness was one of five directors and medical consultants at the Atomic Energy Plant at Oak Ridge, Tennessee.

"Against this background the Government developed its case by presenting testimony in the form of case histories of sixteen persons who had taken the Hoxsey medicine for treatment of internal cancer. Nine of these persons are among those listed in that part of the booklet which we have held to constitute specific representations of cure. We shall not undertake to lengthily detail the voluminous evidence. It followed the general pattern of showing physical examination, the making of the biopsy and pathological examination of the tissue, and dependent upon the facts in the particular case, that, where actual malignancy was present it was neither retarded nor cured by the use of the Hoxsey medicines; or there was in fact no malignancy; and that certain of the persons who had cancer were operated on for cancer, or died, while taking the Hoxsey treatment; that one patient with cancer declined surgery, used the Hoxsey medicine, but died of cancer; and one regressed while taking the medicine but improved with subsequent X-ray therapy. Each of these critical circumstances was shown by the testimony of examinations, diagnoses and result by medical doctors, pathologists, and scientific examination, all had and done in accordance with the generally accepted and approved methods and means of ascertaining and determining the facts in such instances. If such testimony be accepted as credible, it clearly establishes the Government's contention that the Hoxsey drugs in question are not efficacious in the treatment, mitigation and cure of cancer in man, contrary to the general representation of the booklet, and that the specific representation as to nine of those persons listed by name in the booklet are not true in that such persons were not cured of cancer by the use of such drugs.

"The defendants countered the case of the Government with testimony as to twenty-two cases of claimed cancer cure, as well as the testimony of three osteopaths, Dr. Durkee, the director of the clinic, Dr. Macauley, a general practitioner of Jefferson City, Missouri, and Dr. Downs of Denver, Colorado. Mr. Hoxsey did not testify. Eleven of the twenty-two cases concerned alleged cancer of the skin and the result of the use of the Hoxsey powder and salve. Some of these also took the internal medicine, though it is not shown that this had any effect upon the alleged cancer and the testimony is to the effect that the powders and salves were escharotics which destroyed the cancer tissue, as well as the normal tissue. In any event, the Government made no charge with reference to the powder or salve or to external or skin cancer, and contends here, correctly we think, that these eleven cases were irrelevant to the question in issue, which dealt solely with the efficacy of the black and pink drugs taken orally for the cure of internal cancer. In three of the remaining eleven cases of alleged cancer cure the only evidence that the patient actually had cancer when he went to the clinic was the testimony of the witness. Each of these was a patient at the clinic prior to the beginning of Dr. Durkee's employment there in 1946. Over the objection of the Government, they were permitted to testify that they had cancer. In the cases of four of the eight remaining alleged cancer cures the Government introduced medical testimony of doctors who had treated and operated on the patients to show that the cancerous condition had been successfully treated before the patient went to the Hoxsey Clinic. In three of these cases the absence of malignancy was shown by pathological examination. After apparent cure, these patients went to the Hoxsey Clinic and took the liquid medicine. In one of

the cases within fifteen days after the negative result of the biopsy examination had been ascertained, Dr. Durkee, without a biopsy, stated he found cancer. In the four remaining cases the patients were likewise permitted to testify that they had cancer, or had been told that they had cancer, but there is no evidence of biopsy, and any proof of the nature of the disease these patients suffered is dependent upon the diagnosis and testimony of Dr. Durkee. Under these circumstances, the Government contends that in no instance is there reliable scientifically acceptable evidence that the patient had a cancer when the Hoxsey medication was instituted. Dr. Macauley had practiced his profession since 1941 and had spent approximately a year at the Hoxsey Clinic. He admitted that he is not a cancer expert. He conceded that the only proper method of diagnosing a cancer is to make a biopsy and pathological examination of the tissue. Dr. Downs testified to the same effect. Dr. Durkee testified that he did not 'need a biopsy to make a diagnosis of cancer.' Substantially his entire experience and practice with cancer has been at the Hoxsey Clinic where during the past five or six years he has personally examined or treated five or six thousand patients. He personally examines all of the patients, seeing thirty-five to fifty a day, and spending between five and ten minutes with each on the average, though with some longer than others. Of this number, he estimates he has taken between three and four hundred biopsies. Not many were made of patients by other people at his request.

"The above restricted summaries are not stated in an attempt to review in detail a voluminous record, but to show the general nature of the case put forward by the plaintiff and the defendant and to point up the difference in the type of proof presented by the Government to establish the allegations of the complaint, and the type of proof relied upon by the defendant to cast doubt upon the Government's case as thus presented.

"Based upon the claim of supremacy of scientific testimony and pathological examination over the opinions of lay witnesses that they had cancer and were cured, or their hearsay testimony of what doctors had told them of their condition, and likewise over the testimony of Dr. Durkee, who, it is contended, was not only a vitally interested witness, but also without sufficient qualifications as an expert, the Government contends that as to the nine instances of specific misrepresentations its evidence is actually undisputed and requires a decree in its favor. It is also contended that it was prejudicial error for the trial Court to permit laymen to testify that they had, or were cured of, cancer, or as to what a physician had told them as to their condition. The third major contention of the Government is that the trial Court's findings that the Hoxsey drugs are not falsely represented as cancer cures and that they do cure cancer are clearly erroneous.

"We have already stated the effect we think proper to give to the general and specific representations set forth in the booklets, the labeling of the drugs. Our consideration of the record and the nature of the issues involved has led to the firm conclusion that the trial Court's findings of fact that the representations in the labeling were neither false nor misleading, and that the brownish-black and pink colored medicines were efficacious in the cure of cancer in man are clearly erroneous. Thus, even if it be assumed, *arguendo*, that there is *some* measure of conflict in the evidence relating to the falsity of the specific representations referred to above, still, it is clear that a finding that such representations are true is not supported by substantial evidence. It is equally clear that without regard to any general rule of admissibility of the testimony of laymen as to the existence of disease or physical injury or as to the curative effect of drugs,<sup>11</sup> when the subject of investigation is the existence of cancer, the personal testimony of the lay sufferer is entitled to no weight, since the overwhelming preponderance of qualified opinion recognizes that not even the experts can assuredly diagnose this condition without the aid of biopsy and pathological examination. Hearsay testimony of what such a person has been told by a physician is entitled to no greater weight. Except for such testimony and the testimony of the three osteopaths, two of whom did not claim to be experts on the diagnosis

<sup>11</sup> Cf. *United States v. 141 Bottles of Drug Products*, S. D. Texas not reported; affirmed in *Hall v. United States*, 5 Cir., 267 Fed. 795; *Federal Trade Commission v. Kay*, 35 F. 2d, 160, 162.

and treatment of cancer, and the third of whom is a definitely interested witness who testified as to ability to diagnose contrary to all accepted scientific knowledge, the testimony on behalf of the Government in the full and complete establishment of its case of misbranding is not substantially disputed. We think this so-denominated conflicting evidence is wholly insufficient to cast such doubt upon the testimony adduced in behalf of the Government as to authorize the trial Court to find that the Government had failed to carry the burden of establishing the truth of the allegations of its complaint. To the contrary, we think that the evidence in this case, considered as a whole, should, and must, induce a conviction that the finding of the trial Court that the representations were neither false nor misleading is so 'against the great preponderance of the credible testimony that it does not reflect or represent the truth and right of the case.'<sup>12</sup> On the entire evidence we are 'left with the definite and firm conviction that a mistake has been committed.' *United States v. Gypsum Co.*, 333 U. S. 364, 395. We recognize, as we must, that the cause, effect and cure of cancer are so obscure and indefinite that there obtains in the entire subject an area of the unknown. It is nevertheless the duty of a Court in making determination of questions of such great public moment as those which now confront us to give weighty consideration to the experience of the past and the accepted views and findings of science as held and confirmed by such experience and as likewise shown by the weight of the testimony to be applicable to the specific facts of this case. In this, as in other similar matters, that not all, or even little, is known about the subject does not require us to disregard that which is known and established. We do not have for consideration the merits even of any claimed newly discovered, or secret, drug or cure. The case involves the efficacy of only well known drugs. As a cure for cancer these have been weighed and found wanting.

"It was not necessary for the Government to prove that each and every representation in the booklet was false or misleading. The statute seeks to prevent labeling which is false or misleading in any particular. Proof that such representation in the case of at least nine of the persons represented as cured was false establishes the falsity of such representation in a most significant particular. Furthermore, as we have held, the overwhelming weight of the credible evidence requires a conclusion that the representation that the Hoxsey liquid medicines are efficacious in the cure of cancer is likewise false and misleading. The evidence as a whole does not support the finding of the trial Court that 'some it cures, and some it does not cure, and some it relieves somewhat.'

"We do not attempt to set ourselves up as arbiters of what method of treatment the Hoxsey Clinic shall employ. We are not authorized by law to do so. It is our duty to adjudge the merits of the case in the light of the provisions and intent of the Federal Food, Drug and Cosmetic Act, *supra*, which close the channels of interstate commerce against drugs which are misbranded. There is no question in this case but that the drugs, with the accompanying labels, were distributed by the defendants in interstate commerce to patients, as well as to Dr. Downs. It is stipulated that one such shipment was made to a patient only a few days before the beginning of the trial. We find these shipments and the accompanying labels to come within the prohibition of the statute and the finding of the trial Court to the contrary to be clearly erroneous.

"The facts of the case require the issuance of an injunction, and the Court's failure to do so evidences an abuse of discretion. The judgment of the trial Court is reversed, and the cause remanded with direction that the trial Court order an injunction to issue as prayed.

"REVERSED, AND REMANDED, with direction."

On December 8, 1952, the defendants filed with the United States Supreme Court a petition for a writ of certiorari; and, on February 2, 1953, such petition was denied.

The United States District Court for the Northern District of Texas entered a decree on June 29, 1953, permanently enjoining the defendants from directly, or indirectly, introducing and delivering, for introduction into interstate commerce, the drugs which were the subject of the complaint, or any similar

<sup>12</sup> *Sanders v. Leech*, 158 F. 2d. 486.

drugs, and which were misbranded. The decree further provided that the misbranding under Section 502 (a), which was prohibited by the injunction, applied to such drugs, the labeling of which was false and misleading in any particular within the meaning of the Act. It also specifically prohibited the use as labeling of the drugs, the white booklet entitled "Hoxsey Cancer Clinic Specializing in Cancer" consisting of 44 pages and the blue booklet entitled "Hoxsey Cancer Clinic" consisting of 58 pages; also prohibited was the labeling of such drugs which represented, suggested, or implied that the drugs were beneficial, effective, or had value in the cure, mitigation, or treatment of any type of cancer in human beings without appropriate qualifying statements revealing the conflict of medical opinion as to the truth of such representations.

On August 8, 1953, the Government filed with the United States Court of Appeals for the Fifth Circuit a petition for a writ of mandamus to the United States District Court for the Northern District of Texas, based on the district court's failure to comply with the mandate of the court of appeals. On October 22, 1953, the court of appeals handed down the following opinion:

PER CURIAM: "Alleging that, though directed by the mandate of this court to 'order an injunction to issue as prayed,' the district judge had failed and refused to do so, the United States of America filed its petition, praying that a writ of mandamus issue to Judge William H. Atwell, Judge of the United States District Court for the Northern District of Texas, 'To vacate and expunge the final decree of June 29, 1953, so far as it fails to conform to the mandate of this Court, by striking from the said final decree the words reading as follows: "without appropriate qualifying statements revealing the conflict of medical opinion as to the truth of such representations."'"

"A show cause order having issued as prayed in the petition, Judge Atwell filed his answer to the order as follows:

COMES NOW William H. Atwell, Judge of the United States District Court for the Northern District of Texas, in answer to the order made by this Honorable Court, which order is dated February 7th, 1953, and which order is predated before the complained of injunction was signed by me. Such order was not signed until June 29, 1953.

Such order in all respects corresponds to the judgment of this Honorable Court, save and except the paragraph which is now objected to by the government, reading as follows:

"Without appropriate qualifying statements revealing the conflict of medical opinion as to the truth of such representations."

The opinion of this Honorable Court shows distinctly that it recognized that there were different opinions as to the curative value and power of the defendant's remedies.

In addition to such statement by this Honorable Court in its opinion was the great volume of testimony from witnesses in person who appeared and testified that they had been cured of skin cancer by the defendant's treatment and remedies. Photographs of the afflicted persons, both men and women, were offered in evidence, and identified by the respective witnesses as photographs of themselves when they were so suffering. And as they testified in court, there were no such blemishes, or, skin disorders that could be seen.

This statement is made with great respect and with the statement that the McAnnulty healing case, 187 United States, when reexamined, as shown 338 United States, does not do away with the power of the trial court to pass upon the weight and credibility of the testimony.

In the oral opinion which I rendered at the conclusion of the trial of the case, I held the government had not satisfied the burden of proof resting upon it.

With great respect, I am  
Yours very earnestly,

(S.) W. H. Atwell,  
United States District Judge.

"Thereafter an application was made to this court by the Hoxsey Cancer Clinic and Harry M. Hoxsey for leave to intervene in the mandamus proceeding. In the alternative, if such leave was denied, its counsel sought leave to file a brief amicus curiae. Leave to intervene was denied, leave to file a brief amicus curiae was granted, and the brief was filed.

"We are of the clear opinion, for the reasons hereafter briefly stated, that the decree of the court to the extent complained of in the petition is in direct conflict with our mandate, that the answer of the district judge to the show cause order not only presents no reason why the mandate should not issue as prayed, but, on the contrary, shows that it should, and that the complained of paragraphs should be stricken and expunged from the decree.

It is settled that if the lower court misconstrues a decree of an appellate court and does not give full effect to the mandate his action may be controlled by a writ of mandamus. Whatever was before the appellate court and disposed of by the decree is considered as finally settled and becomes the law of the case. The trial court must carry the decree into execution according to the mandate. In *re Potts*, Petitioner, 166 U. S. 263. [In *re N. V. Zuid-Hollandsche Scheepvaart Mattschappij of Rotterdam*, 64 F (2) 915.]

"The district judge, in his letter attached as Exhibit 'C' to the petition, in which he stated that he would sign the decree presented by the United States for entry, recognized this to be the law. In that letter he stated, 'The order seems to be in accordance with the direction of the Circuit Court of Appeals and I will sign the order on June 29th, when the case is set down for final disposition.'

"Instead, however, of signing the order as presented, he added to it language which had the effect of emasculating, if not of completely nullifying, the mandate. This is made plain not only by a comparison of mandate and decree but by the respondent's answer. Conceding in it that the complained of addition to the decree, 'without appropriate qualifying statements revealing the conflict of medical opinion as to the truth of such representations,' does not correspond to the judgment of this court, he attempts to justify its use in his decree by challenging the correctness of the mandate. Stating, 'the opinion of this Honorable Court shows distinctly that it recognized that there were different opinions as to the curative value and power of the defendant's remedies. \* \* \* that the McAnnulty healing case, 187 United States, when re-examined, \* \* \* does not do away with the power of the trial court to pass upon the weight and the credibility of the testimony. \* \* \* In the oral opinion which I rendered at the conclusion of the trial of the case, I held the government had not satisfied the burden of proof resting upon it,' he asserts in effect that he has a right to correct our mandate to conform to these views.

"Thus reasserting the correctness of his judgment, which this court had reversed, and the incorrectness of our judgment reversing it, the respondent instead of confessing error in not accepting and giving effect in his decree to the judgment of reversal, defends the reinstatement of his own judgment to the extent accomplished by the addition to the decree. This he may not do.

"In accordance, however, with the practice of this court, which proceeds on the assumption that the district judge will conform to this court's directions herein contained, without the necessity of issuing the writ prayed for, In *re N. V. Zuid-Hollandsche Scheepvaart Mattschappij of Rotterdam*, supra, a copy of this opinion will be certified to the district judge for his guidance, and the writ will not at this time issue."

ATWELL, *District Judge*:

#### DECREE OF PERMANENT INJUNCTION

"Pursuant to the Mandate of the United States Court of Appeals for the Fifth Circuit dated July 31, 1952, directing that an order for injunction issue in this case as prayed, the following Injunction is ordered to issue:

"ORDERED AND DECREED That Hoxsey Cancer Clinic, a partnership doing business at Dallas, Texas, and Harry M. Hoxsey, of Dallas, Texas, and

their agents, servants, employees, representatives, attorneys and assigns and all persons in active concert or participation with them are perpetually enjoined from directly or indirectly introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce in violation of 21 U. S. C. 331 (a) the following drugs, so long as they are misbranded within the meaning of 21 U. S. C. 352 (a) as hereinafter set forth.

"The drugs referred to are:

"(1) A brown or blackish-brown mixture which contains potassium iodide, sugar, water, and extracts from one or more of the following: cascara sagrada, common buckthorn, alfalfa, red clover blossoms, and northern prickly ash;

"(2) a pink mixture which contains potassium iodide and elixir lactate of pepsin; and

"(3) any similar drugs.

"The misbranding under 21 U. S. C. 352 (a) which is prohibited by this injunction applies to said drugs, or any of them, the labeling of which is false or misleading in any particular within the meaning of said Act, and the use as labeling on said drugs, or any of them, of a white booklet entitled 'Hoxsey Cancer Clinic Specializing in Cancer,' consisting of 44 pages and a blue booklet entitled 'Hoxsey Cancer Clinic' consisting of 58 pages, which were involved in this action, are specifically prohibited; also, the labeling thereof which represents, suggests or implies that the drugs are beneficial, effective or have value in the cure, mitigation, or treatment of any type of cancer in human beings is prohibited.

"IT IS FURTHER ORDERED AND DECREED that costs are assessed against the defendants in favor of the plaintiff."

In accordance with the above opinion of October 22, 1953, the United States District Court for the Northern District of Texas entered, on October 26, 1953, a decree of permanent injunction against the defendants identical to its decree of June 29, 1953, except for the deletion of that portion which the appellate court had determined to be contrary to its mandate.

Following the appellate court's decision of October 22, 1953, in which leave was denied to the defendants to intervene in the mandamus proceedings, the defendants filed a petition for a writ of certiorari with the United States Supreme Court to review the appellate court's denial of leave to intervene. On November 30, 1953, the Supreme Court denied the petition for certiorari.

An appeal to the United States Court of Appeals for the Fifth Circuit was taken by the defendants from the district court's decree of October 26th; and, after a hearing in the matter, the appeal was dismissed by the appellate court on May 14, 1954.

On August 24, 1954, costs of \$5,520.08 incurred by the Government in the injunction action were taxed against the defendants. Thereafter, a motion to retax the costs was filed by the defendants, and on September 9, 1954, the motion was overruled by the district court.

**4655. Testo-Glan and Fem-Tone.** (F. D. C. No. 35841. S. Nos. 40-242 L, 53-947 L.)

INFORMATION FILED: 7-16-54, E. Dist. N. Y., against Leo Shine, t/a Glanex Products and Medical Products, Floral Park, N. Y.

SHIPPED: Between 11-20-53 and 4-2-54, from New York to Arizona and Missouri.

LABEL IN PART: (Btl.) "Testo-Glan Male Formula Regular Strength Contents 60 Capsules Each capsule contains—Hormonal activity as found in wheat—Testosterone (Male Sex Hormone). . . . 0.067 mcg. Vitamin E. . . . 0.034 mgms. Survival Factor. . . . Vitamin B<sub>1</sub> 5 mg. 500% MDR. Vitamin B<sub>2</sub> 3.5 mg. 175% MDR. Niacinamide . . . 15 mg." and "Fem-Tone Female Formula Contents 60 Capsules Each capsule contains—Hormonal activity as